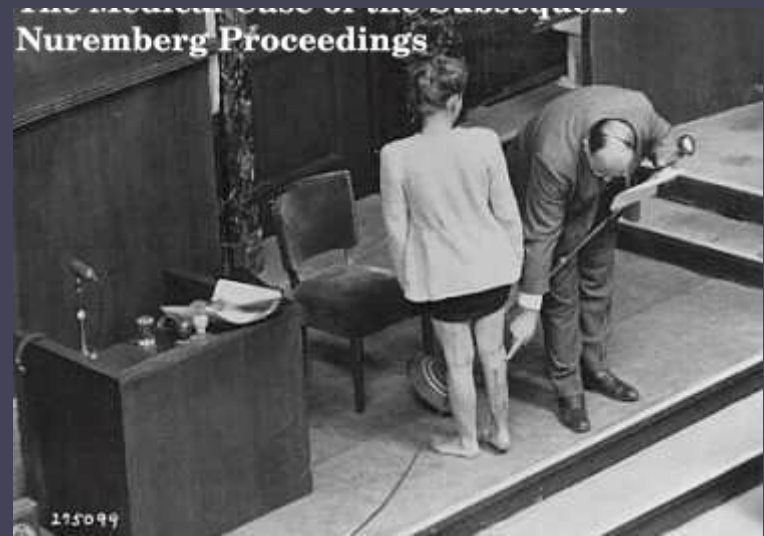


Lederer part II





First principle


. The voluntary consent of the human subject is absolutely essential.

Strictly interpreted, the first principle would eliminate experiments on children, prisoners, the dying, the mentally ill

efforts to create a more workable code

The Declaration of Helsinki (1964)

Beecher concerned about new
researchers who fail to understand
their responsibilities

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Who were the research subjects in Beecher's 22 examples?

“mentally defective” children
mentally retarded and delinquent children
the very elderly
soldiers in the armed forces
charity patients
terminally ill
alcoholics
children and newborns
patients at the NIH Clinical Center

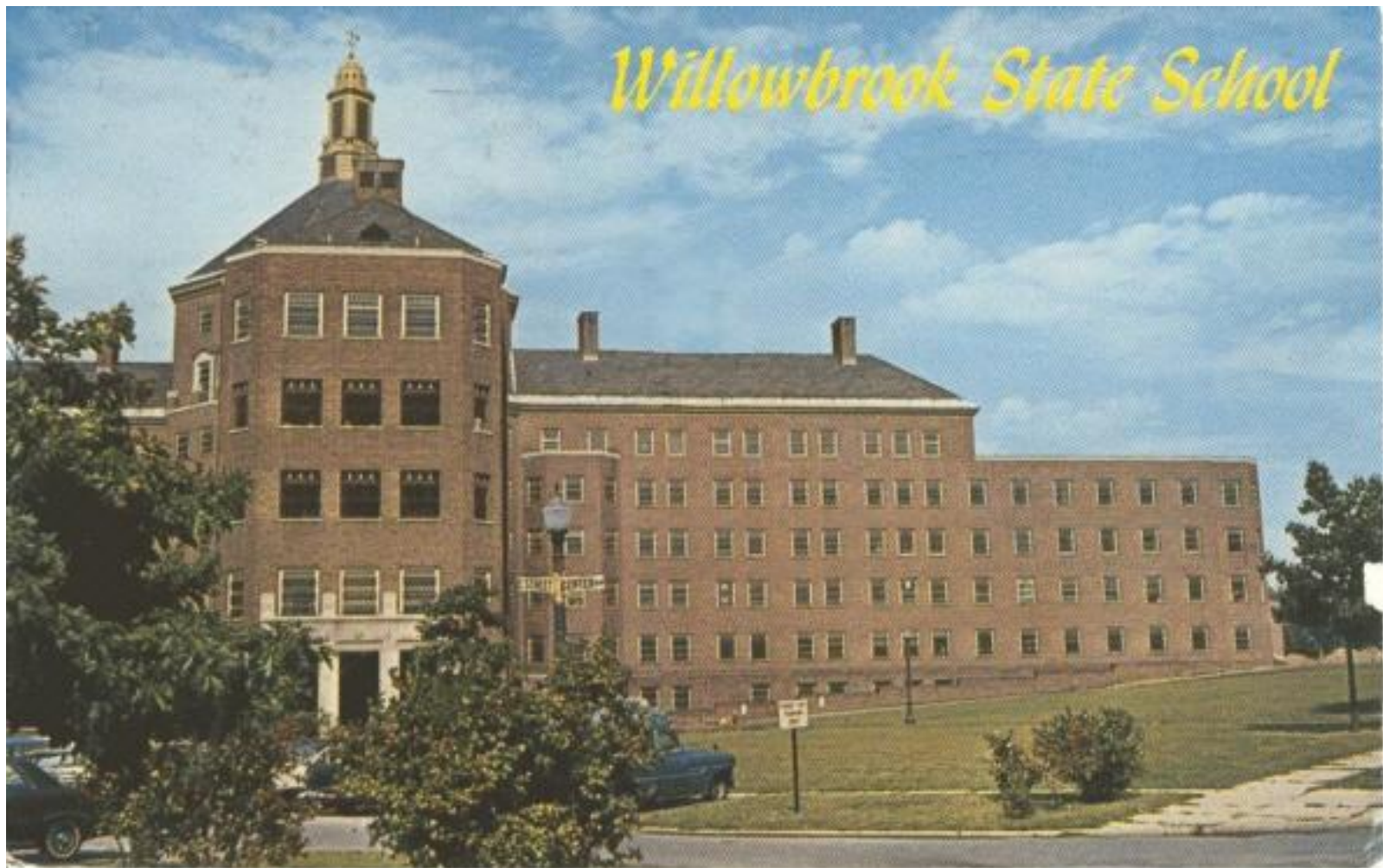
Example 4

Study of effects of new antibiotic for treating
acne using juvenile delinquents

the drug associated with liver problems

teenagers undergo repeated liver biopsies

Willowbrook State School





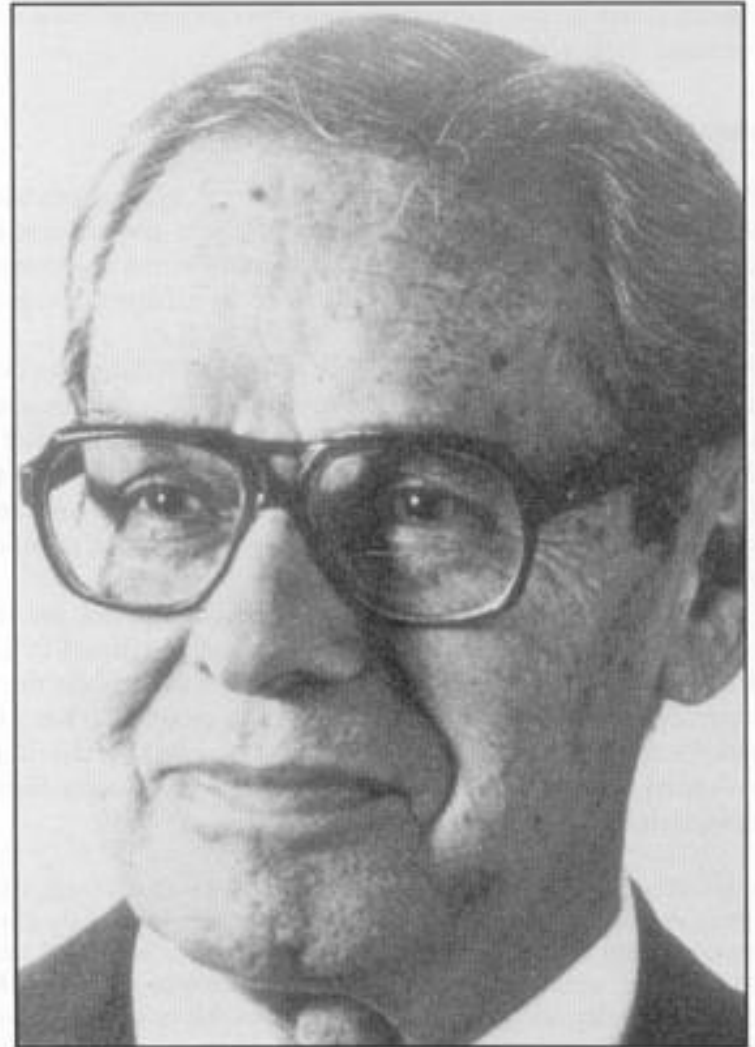
Dr. Saul Krugman et al begin studies to acquire information about the natural history of hepatitis and work toward vaccine

Willowbrook studies

Newly admitted children (whose parents give consent) are given intramuscular injections of hepatitis or “milkshakes” with hepatitis



Krugman continued
to defend the studies
but
issues persisted about
informed consent,
coercion, and study
design (withholding
gamma globulin)



SAUL KRUGMAN, M.D.

Example 17

Jewish Chronic Disease Hospital case

Funded by USPHS and
American Cancer Society

Injections of live cancer
cells into elderly patients
without consent

"did not wish to stir up any
unnecessary anxieties in
the patients" who had
"phobia and ignorance"
about cancer.

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER

The Associated Press

July 25, 1972

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

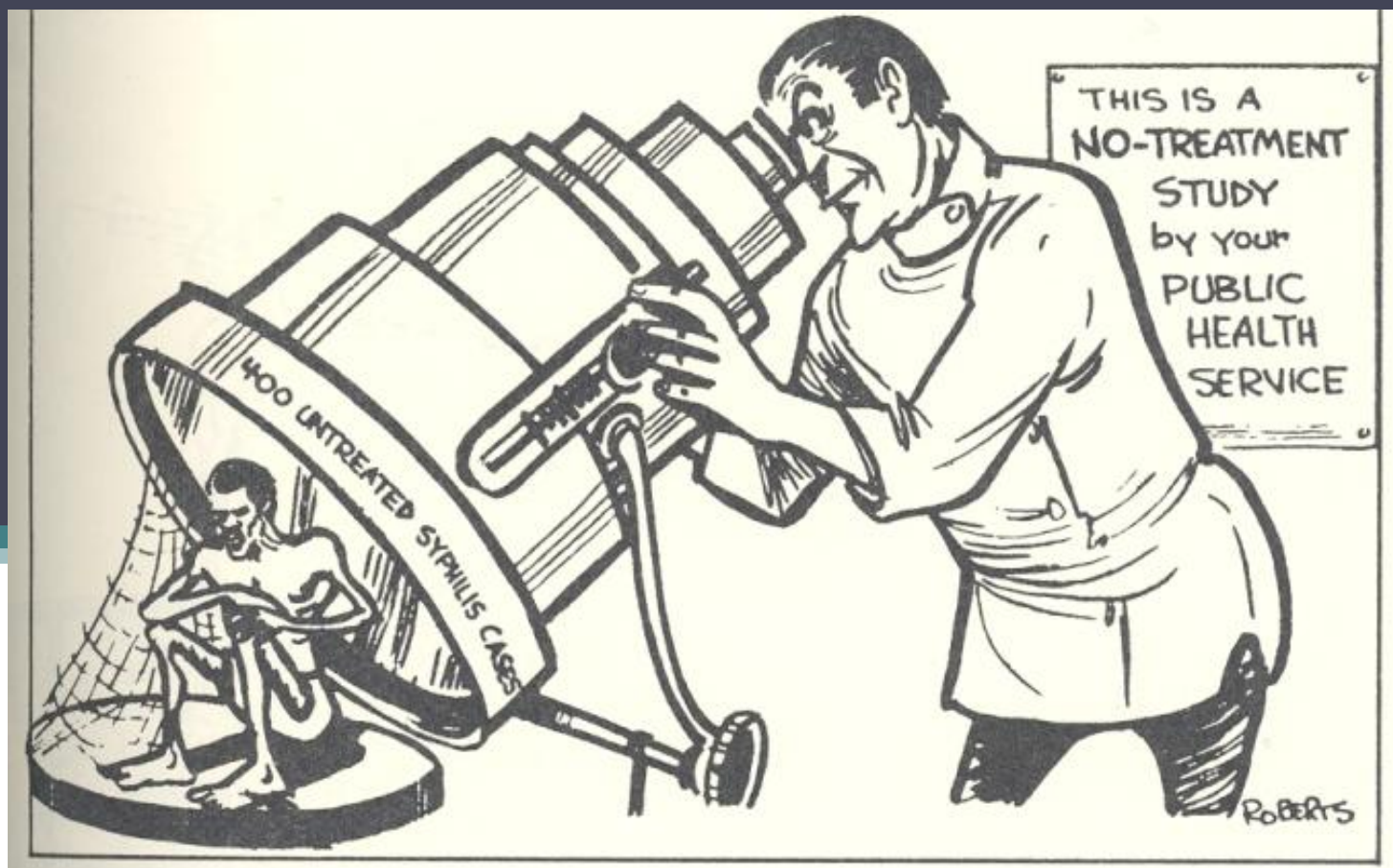
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,



Study begins in 1932



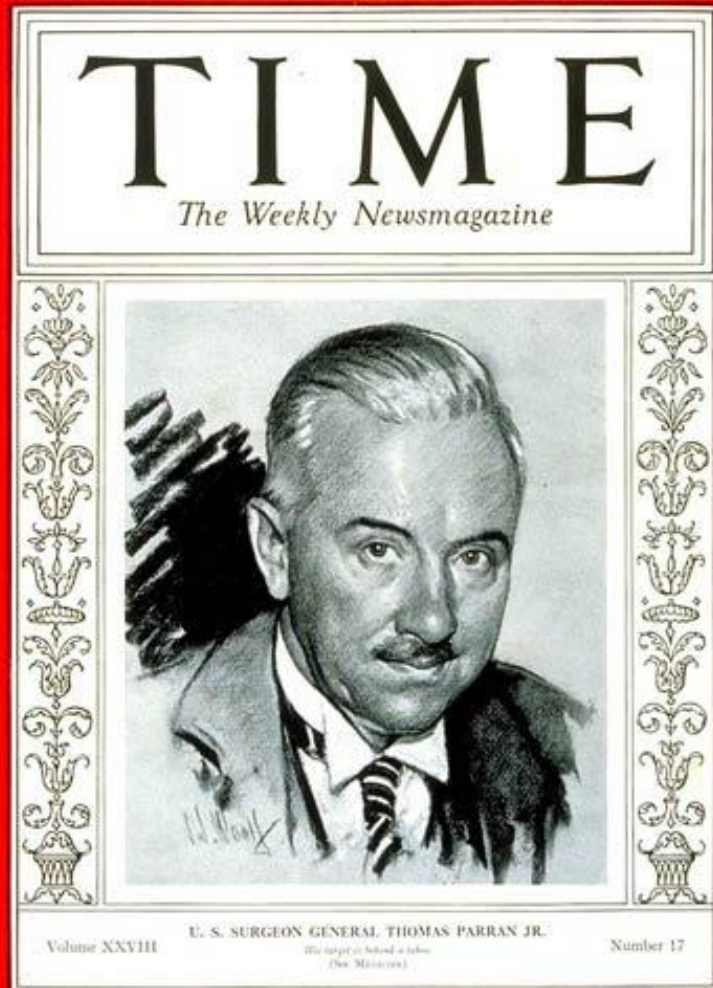
(Courtesy National Archives)



PHS Surgeon General Thomas Parran,

Shadow on the Land

Head of PHS, 1936-
1948



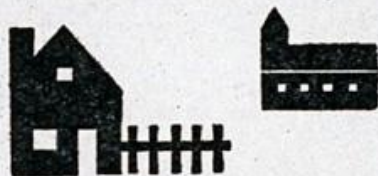
INCIDENCE OF SYPHILIS AMONG NEGROES



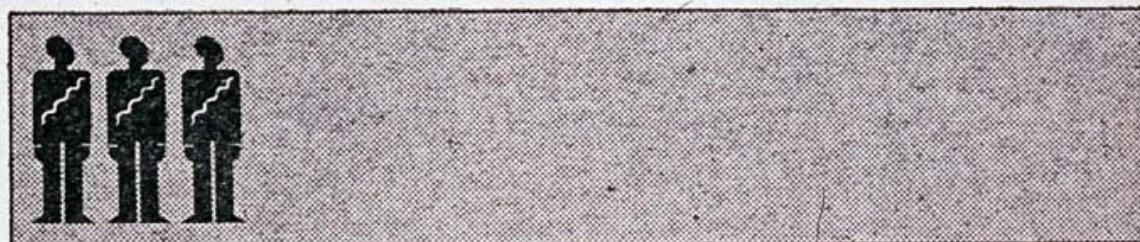
MACON COUNTY, ALA.



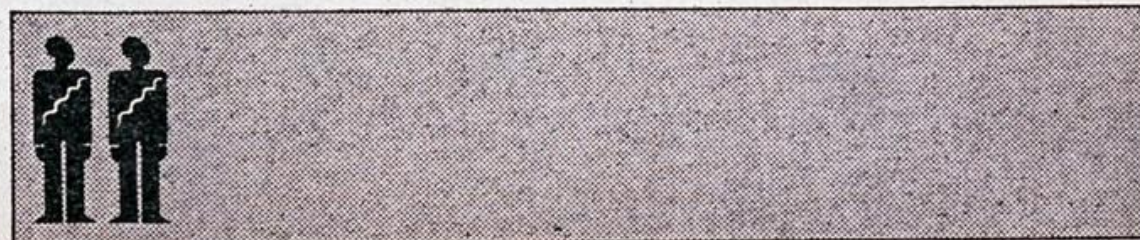
BOLIVAR COUNTY, MISS.



ALBEMARLE COUNTY, VA.



MEHARRY UNIVERSITY, TENN.



Each symbol represents 3% of all Negroes studied

PICTORIAL STATISTICS, INC.

From treatment to “a study in nature”



Dr. Raymond
Vonderlehr offers
Negro men “last
chance for special free
treatment” for their
“bad blood”

Lumbar puncture (to obtain spinal fluid for diagnosis)







World War II

- PHS asks Tuskegee draft board to exempt the men in the study from the draft
- They serve in another war

Nurse Eunice Rivers



Nurse Rivers

obtains permission
for autopsy

easier when a burial
stipend of \$50 is
provided

only one refusal in
140 requests

Figure 3. An unaltered view. Nurse Eunice Rivers measures a participant in the TSUS. Dr. Stanley Schuman records the data. The photograph was taken in the TVAH in February 1952. (National Archives, CDC, East Point, GA)



TABLE I. TABULAR LISTING OF DIFFERENCES IN THE UNTREATED SYPHILIS STUDIES IN ALABAMA AND IN NORWAY

	ALABAMA	NORWAY
Study population composition	Rural Negro men	White men and women
Control	Nonsyphilitic controls observed	No controls
Percentage autopsied of those who have died	63.3 per cent	24.3 per cent
Patient motivation for study participation	Volunteers with social incentives	Sickness and disability
Treatment status	Small amounts, especially in younger men	Less treatment available, especially in early years of study
Clinical facilities	Newer x-ray, EKG, and serologic techniques	Best medical facilities of the time (1925-1927)
Spinal fluid examination	Most of the syphilitic patients had spinal fluid examinations at start of study	No routine spinal fluid examination reported
Selection of patient material	Acute syphilis and younger patients treated and omitted at start of study; early and late latent patients studied and followed	Only early, untreated syphilis included

1954

”for the first time, men in the study identified as “volunteers with social incentives”

U. S. PUBLIC HEALTH SERVICE

25

This certificate is awarded to

In grateful recognition of 25 years
of active participation in the
Tuskegee medical research study.

Awarded 1958



LeRoy C. Burney

Surgeon General

1969

CDC convenes a blue-ribbon panel to determine whether Tuskegee study should continue
only physician not familiar with the Study
argues that the experiment should end and the
men receive treatment
the Study continues until 1972

Study Revealed July 25, 1972





- Kennedy holds hearings on human experimentation including the TSS
- Legislation passed 1974
- National Research Act

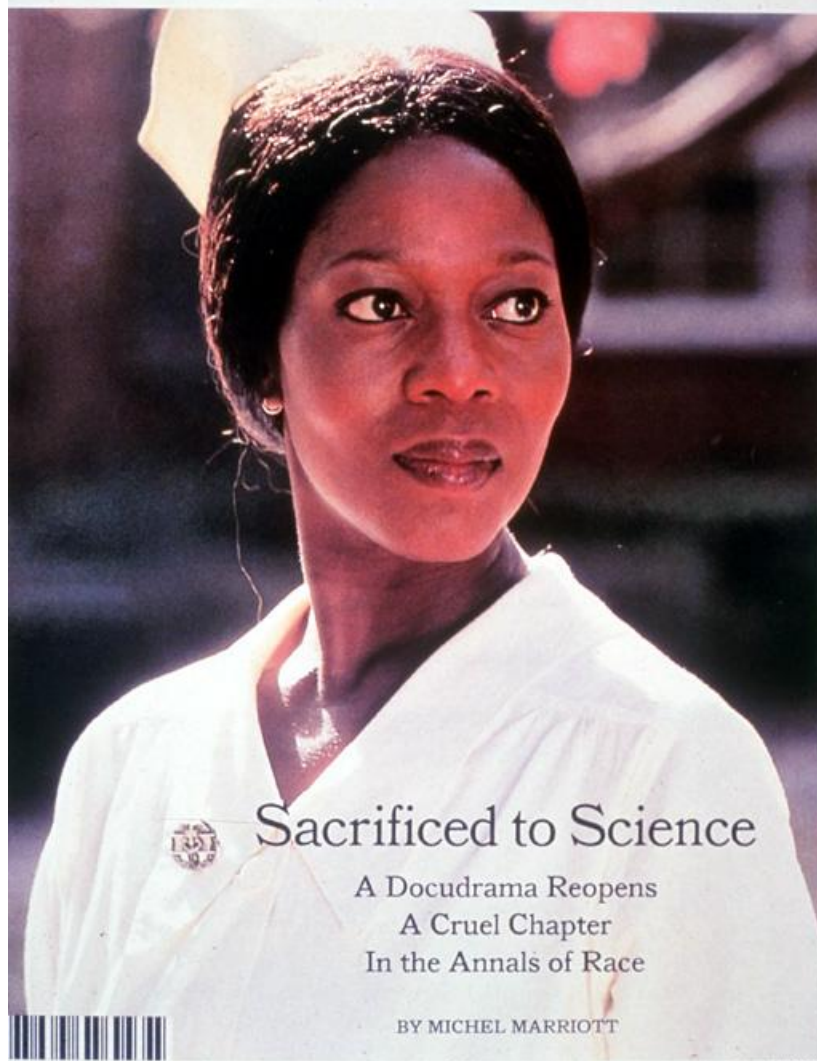
1974 National Research Act

creation of a National Commission to study the moral issues posed by human experimentation

new federal regulations for IRBs and written informed consent

Television

FEBRUARY 16-22



Sacrificed to Science

A Docudrama Reopens
A Cruel Chapter
In the Annals of Race

BY MICHEL MARRIOTT



Persistent stories about the
deliberate infection of the men in
Tuskegee with syphilis

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The AIDS 'Plot' Against Blacks

Bizarre as it may seem to most people, many black Americans believe that AIDS and the health measures used against it are part of a conspiracy to wipe out the black race.

A survey of black church members in 1990 found that an astonishing 35 percent believed AIDS was a form of genocide. A New York Times/WCBS-TV News poll in 1990 found that 1 black in 10 believes the AIDS virus was "deliberately created in a laboratory in order to infect black people" and an additional 2 in 10 thought that might be so. A Gallup/Newsweek poll in March produced similar results.

Even some dedicated black health workers engaged in the fight against AIDS decline to disavow these fears. Testifying before the National Commission on AIDS, one said that "until proven otherwise" she considered AIDS a man-made disease.

Worse yet, the treatments and preventives against AIDS have become suspect. Some blacks believe that AZT, the harsh drug used to combat the disease, is a plot to poison them

... that campaigns urging use of condoms, the best way to prevent sexual transmission, are a scheme to reduce the number of black babies ... that distributing clean needles to slow transmission among addicts is a plot to encourage drug abuse.

At its most destructive, the paranoia causes many blacks to avoid medical treatment. Unless black and Hispanic leaders play a more vigorous role in countering the fears and mistrust, it will become ever harder to slow the epidemic.

The task is urgent because the disease is now spreading most rapidly among minorities. Last year, for the first time, the number of AIDS cases reported for minorities exceeded the number for whites. Most worrisome for the future, blacks account for a majority of AIDS cases in women and children. "AIDS in future generations may be primarily a disease of black people," the New York Department of Health warned last month.

Yet the response to this growing crisis has been sluggish. Financially pressed minority organizations and local governments have little energy for fighting AIDS, especially given the stigma attached to its main victims, homosexuals and drug addicts. But whether financing for minority AIDS programs has lagged behind white programs, as some black leaders charge, is not clear. Federal and state funds to minority AIDS organizations have gone up and the Government's central programs, like counseling and testing services, have huge minority caseloads.

No programs, even if well financed, will succeed without a change in attitudes. Thus it is welcome news that the New York State Health Department, with the help of black politicians and community leaders, has started a media campaign to encourage blacks to mobilize against AIDS.

The campaign rightly stresses that AZT and condoms are not plots against blacks. But it refuses to counteract the paranoia about AIDS as genocide, saying only that no matter

how AIDS got started, there are ways to stop it. Campaign officials reasoned that few blacks would believe government denials anyway. But surely black leaders and public figures with high credibility, such as Magic Johnson, the basketball star, could do much to discredit the pernicious and dispiriting rumors.

Meanwhile, Federal, state and local health officials need a far better assessment of the flow of AIDS money into minority communities and stronger programs to fight the disease there. Costly drug treatment ought to be provided to all who seek it, an investment that would yield dividends far beyond slowing the spread of AIDS. And more vigorous outreach programs might persuade more individuals to avoid risky behavior.

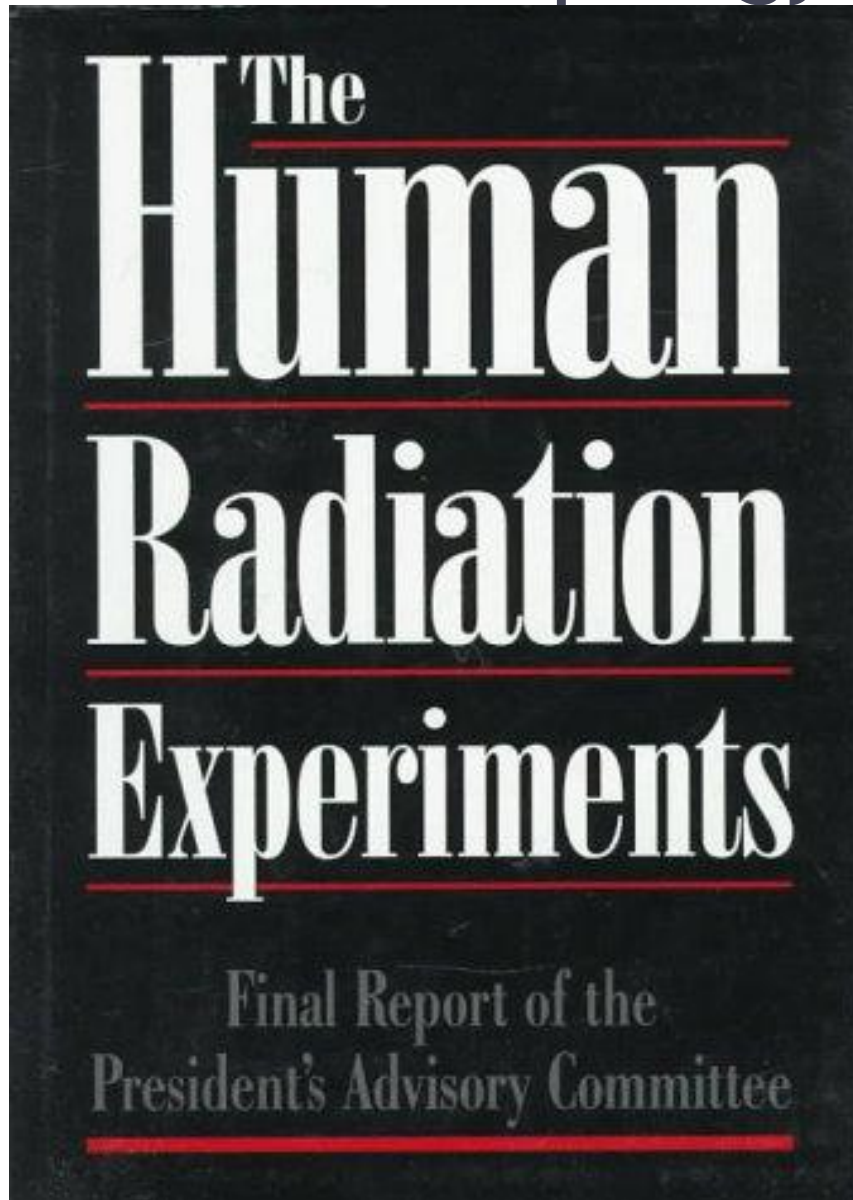
As white Americans, shaken by the riots in Los Angeles, search for ways to help afflicted and distrustful minorities, there's no wiser way to start than AIDS. A failure to treat and prevent AIDS among minorities: That would be the true genocide.

The Plague Spreads

A rising toll among minorities



Presidential apology 1995



White House Apology for the Syphilis Study, May, 1997





White House apology ceremony, 16 May 1997. Participants and survivors of the study (first row): Herman Shaw, Fred Simmons, Charles Pollard, Frederick Moss, Carter Howard. White House officials (back row): U.S. Surgeon General David Satcher, President William J. Clinton, Vice-President Albert Gore.

Wielding the “Tuskegee Analogy”

In 1997 *NEJM* acting editor Marcia Angell compares placebo-controlled trials for preventing vertical transmission of HIV from mothers to infants to the Tuskegee Study

2001

Maryland State Supreme Court rules that families can sue the Kennedy-Krieger Institute (JHMI), comparing the research on effects of lead paint on children to both Nazi experiments and the Tuskegee Study.

President Bush vetoes stem cell research bill, summer 2006

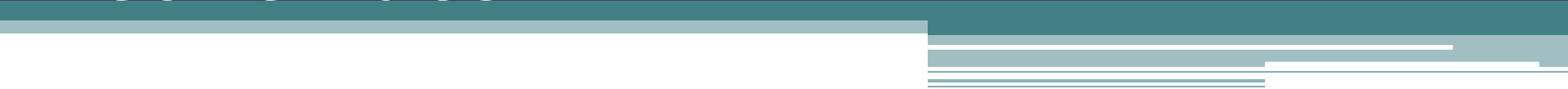
research on human stem cells

“constitutes a grave violation of human rights just as we saw in the Tuskegee experiments here in the United States and in the Nazi experiments of World War II.”



Some characterize the
Tuskegee Syphilis Study
as the American
Holocaust

Scandal, tragedy and revelation continues

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2011

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“ETHICALLY IMPOSSIBLE” STD Research in Guatemala from 1946 to 1948

Presidential Commission
for the Study of Bioethical Issues

September 2011



John Cutler



John G. Cutler
From the National Library of Medicine

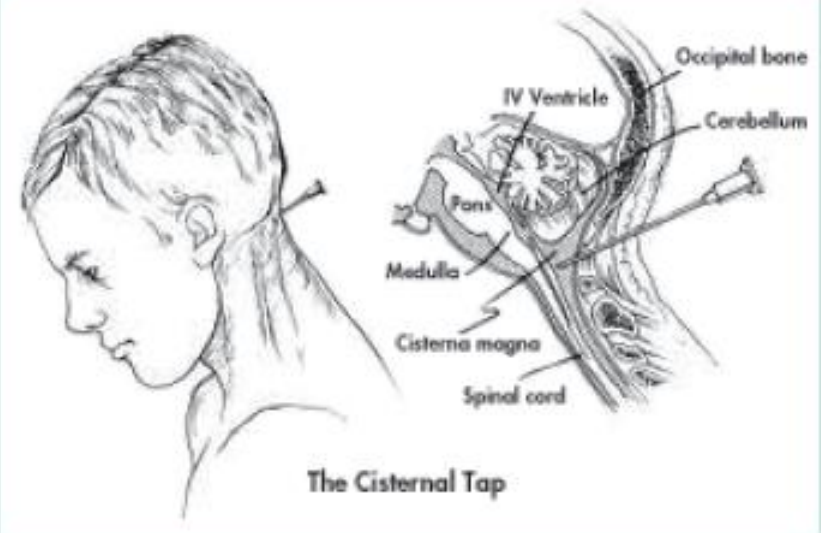
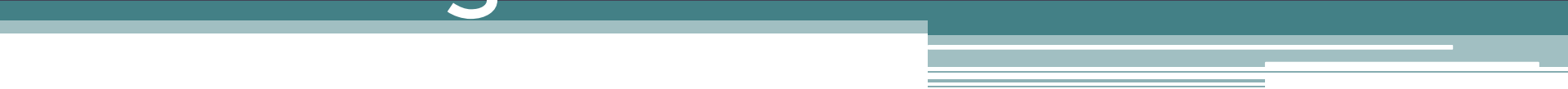


Diagram of a cisternal puncture.
From Alexander G. Reeves, M.D. and Rand S. Swenson, M.D., Ph.D., "Disorders of the Nervous System"

“I saw Doctor Parran on Friday [February 14] and he wanted to know if I had had a chance to visit your project. Since the answer was yes, he asked me to tell him about it and I did so to the best of my ability. He was familiar with all the arrangements and wanted to be brought up to date on what progress had been made. As you well know, he is very much interested in the project and a merry twinkle came into his eye when he said, ‘You know, we couldn’t do such an experiment in this country.’”⁵⁸¹

Learning the past,
living with the past,
forming the future

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